

Please amend the claims as noted below wherein language to be added is indicated with underline and language to be deleted is indicated with ~~strikethrough~~.

1. (Original) A method for the local treatment of a vulvovaginal candidiasis condition diagnosable by a KOH smear test or other fungal speciation test, which comprises:

treating said vulvovaginal candidiasis condition caused by a species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae* by applying to the vaginal tissue of a human a formulation comprising:

about 35 to about 45% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 5 to about 11% w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl-3-oleate; about 0.5 to about 5% w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide; about 0.001 to about 1% w/w methylparaben; about 0.001 to about 1% w/w propylparaben; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate; and

wherein the treatment is a single dose treatment.

2. (Original) The method according to claim 1, wherein said formulation further comprises:

about 38 to about 40% w/w sorbitol solution; about 4 to about 6% w/w propylene glycol; about 0.01 to about 0.5% w/w edetate disodium; about 6 to about 9% w/w mineral oil; about 2 to about 3% w/w polyglyceryl-3-oleate; about 2 to about 3% w/w glyceryl monoisostearate; about 0.01 to about 0.8% w/w microcrystalline wax; about 0.09 to about 0.9% w/w silicon dioxide; about 0.01 to about 0.5% w/w methylparaben; about 0.01 to about 0.5% w/w propylparaben; about 30 to about 40% w/w water; and about 1.5 to about 3.5% w/w butoconazole nitrate.

3. (Original) The method according to claim 2, wherein said formulation further comprises:

about 39.978% w/w sorbitol solution; about 5% w/w propylene glycol; about 0.05% w/w edetate disodium; about 8.032% w/w mineral oil; about 2.713% w/w polyglyceryl-3-oleate; about 2.713% w/w glyceryl monoisostearate; about 0.452% w/w microcrystalline wax; about 1.013% w/w silicon dioxide; about 0.18% w/w methylparaben; about 0.05% w/w propylparaben; about 37.819% w/w water; and about 2.0% w/w butoconazole nitrate.

4. (Original) The method according to claim 3, wherein the species is *C. glabrata*.

5. (Original) The method according to claim 3, wherein the species is *C. tropicalis*.

6. (Original) A method for the treatment of a vaginal fungal condition, which comprises:

administering a single dose composition comprising about 38 to about 40% w/w sorbitol solution; about 4 to about 6% w/w propylene glycol; about 0.01 to about 0.5% w/w edetate disodium; about 6 to about 9% w/w mineral oil; about 2 to about 3% w/w polyglyceryl-3-oleate; about 2 to about 3% w/w glyceryl monoisostearate; about 0.01 to about 0.8% w/w microcrystalline wax; about 0.09 to about 0.9% w/w silicon dioxide; about 0.01 to about 0.5% w/w methylparaben; about 0.01 to about 0.5% w/w propylparaben; about 30 to about 40% w/w water; and about 1.5 to about 3.5% w/w butoconazole nitrate;

wherein the vaginal fungal condition is a vulvovaginal candidiasis condition caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*, and

wherein the ratio of polyglyceryl-3-oleate to glyceryl monoisostearate is about 1:0.1-10.

7. (Original) The method according to claim 6, wherein the species is *C. glabrata*.

8. (Original) The method according to claim 6, wherein the species is *C. tropicalis*.

9. (Original) A method for the treatment of an unidentified vulvovaginal fungal condition, which comprises:

administration to said fungal condition a bioadhesive, single dose treatment formulation comprising from about 0.500 to about 5.000% w/w butoconazole nitrate; and

wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

10. (Original) The method according to claim 9, wherein said formulation further comprises: about 35 to about 45% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 5 to about 11% w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl-3-oleate; about 0.5 to about 5% w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide;

about 0.001 to about 1% w/w methylparaben; about 0.001 to about 1% w/w propylparaben; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate.

11. (Original) The method according to claim 10, wherein said formulation further comprises:

about 38 to about 40% w/w sorbitol solution; about 4 to about 6% w/w propylene glycol; about 0.01 to about 0.5% w/w edetate disodium; about 6 to about 9% w/w mineral oil; about 2 to about 3% w/w polyglyceryl-3-oleate; about 2 to about 3% w/w glyceryl monoisostearate; about 0.01 to about 0.8% w/w microcrystalline wax; about 0.09 to about 0.9% w/w silicon dioxide; about 0.01 to about 0.5% w/w methylparaben; about 0.01 to about 0.5% w/w propylparaben; about 30 to about 40% w/w water; and about 1.5 to about 3.5% w/w butoconazole nitrate.

12. (Original) The method according to claim 10, wherein said formulation further comprises:

about 39.978% w/w sorbitol solution; about 5% w/w propylene glycol; about 0.05% w/w edetate disodium; about 8.032% w/w mineral oil; about 2.713% w/w polyglyceryl-3-oleate; about 2.713% w/w glyceryl monoisostearate; about 0.452% w/w microcrystalline wax; about 1.013% w/w silicon dioxide; about 0.18% w/w methylparaben;

about 0.05% w/w propylparaben; about 37.819% w/w water; and about 2.0% w/w butoconazole nitrate.

13. (Original) The method according to claim 12, wherein the species is *C. glabrata*.

14. (Original) The method according to claim 12, wherein the species is *C. tropicalis*.

15. (Original) The method according to claim 10, wherein the bioadhesive formulation minimizes leakage from the vaginal cavity of a human.

16. (Original) The method according to claim 10, wherein the treatment provides peak plasma levels of the butoconazole nitrate at about 6 to about 48 hours after administration and retains activity for at least 4 days.

17. (Currently Amended) A method for the treatment of a fungal condition diagnosable by KOH smear test or other fungal speciation test, which comprises:

~~application~~ applying to a vulvovaginal candidiasis condition caused by a member selected from the group consisting of *Candida*

*dubliniensis*, *Candida tropicalis*, *Candida glabrata*, *Candida parapsilosis*, mycelial *Candida*, *Candida krusei*, and *Candida lusitaniae* and mixtures thereof of a treatment comprising:

about 35 to about 45% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 5 to about 11% w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl-3-oleate; about 0.5 to about 5% w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide; about 0.001 to about 1% w/w methylparaben; about 0.001 to about 1% w/w propylparaben; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate.

18. (Original) The method according to claim 17, wherein the treatment is a single dose treatment.

19. (Currently Amended) A method for the local treatment of an unidentified vaginal fungal condition comprising:

administering a single administration of a composition consisting essentially of: about 38 to about 40% w/w sorbitol solution; about 4 to about 6% w/w propylene glycol; about 0.01 to about 0.5% w/w edetate disodium; about 6 to about 9% w/w mineral oil; about 2 to about 3% w/w polyglyceryl-3-oleate; about 2 to

about 3% w/w glyceryl monoisostearate; about 0.01 to about 0.8% w/w microcrystalline wax; about 0.09 to about 0.9% w/w silicon dioxide; about 0.01 to about 0.5% w/w methylparaben; about 0.01 to about 0.5% w/w propylparaben; about 30 to about 40% w/w water; and about 1.5 to about 3.5% w/w butoconazole nitrate[[.]]; and

wherein the administration is to a vulvovaginal candidiasis condition caused by any member selected from the group consisting of C. dubliniensis, C. tropicalis, C. glabrata, C. parapsilosis, C. krusei, and C. lusitaniae.

20. (Original) The method according to claim 19, wherein the species is C. glabrata.

21. (Original) The method according to claim 19, wherein the species is C. tropicalis.

22. (Currently Amended) A method for the treatment of a fungal condition diagnosable by KOH smear test or other fungal speciation, comprising:

treating a candidiasis condition caused by a species selected from the group consisting of C. dubliniensis, C. tropicalis, C. glabrata, C. parapsilosis, C. krusei, and C. lusitaniae by applying to the vaginal tissue a multiphase formulation in a single dose;



wherein the multiphase formulation comprises:

a hydrophilic phase, which comprises: about 38 to about 40% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate; and

a hydrophobic phase which comprises about 5 to about 11% w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl-3-oleate; about 0.5 to about 5% w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide; about 0.001 to about 1.000% w/w methylparaben; and about 0.001 to about 1% w/w propylparaben.

23. (Original) The method according to claim 22, wherein the hydrophobic phase and hydrophilic stage for a bioadhesive dosage form provides peak plasma levels of butoconazole nitrate at about 6 to about 48 hours and retains activity for at least 4 days.

24. (Currently Amended) A method for the treatment of an ~~undiagnosable~~ unidentified vulvovaginitis condition comprising:

treating a condition caused by a species of *Candida* selected from the group consisting of *C. dubliniensis*, *C. tropicalis*, *C. glabrata*, *C. parapsilosis*, *C. krusei*, and *C. lusitaniae* by applying to the vaginal tissue a multiphase formulation in a single dose to

provide a *Candida* species kill rate of about 50 to about 100% for a period of at least about 4 days.

25. (Original) The method according to claim 24, wherein the multiphase formulation is administered via an applicator device which is designed to apply the formulation evenly over the vaginal tissue of a human.

26. (Original) A method according to claim 24, wherein the species is *C. glabrata*.

27. (Original) A method according to claim 24, wherein the species is *C. tropicalis*.